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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/804,822  | 03/19/2004  | Lawrence W. Stanton  | 135/003P            | 7106             |
| 22869   | 7590        | 08/18/2006           | EXAMINER            |                  |
| GERON CORPORATION<br>230 CONSTITUTION DRIVE<br>MENLO PARK, CA 94025 |             |                      | CHEN, SHIN LIN      |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |

1632

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/804,822

Applicant(s)

STANTON ET AL.

Examiner

Shin-Lin Chen

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7, 10-12, 14 and 17-20, drawn to a method for determining the extent of differentiation in a population of isolated human embryonic stem (hES) cells comprising detecting or measuring two or more markers preferentially expressed in undifferentiated hES cells and one or more markers preferentially expressed after differentiation of the hES cells, wherein the markers are detected by antibody assay, classified in class 435, subclass 7.1.
  - II. Claims 1, 2, 4-9, 14 and 17-20, drawn to a method for determining the extent of differentiation in a population of isolated human embryonic stem cells comprising detecting or measuring two or more markers preferentially expressed in undifferentiated hES cells and one or more markers preferentially expressed after differentiation of the hES cells, wherein the markers are detected at the mRNA level by PCR amplification, classified in class 435, subclass 6.
  - III. Claims 1, 13 and 14, drawn to a method for determining the extent of differentiation in a population of isolated human embryonic stem cells comprising detecting or measuring two or more markers preferentially expressed in undifferentiated hES cells and one or more markers preferentially expressed after differentiation of the hES cells, wherein some markers are detected at mRNA level and some markers are detected at the antigen expression level, classified in class 435, subclasses 6 and 7.1.

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- IV. Claim 15, drawn to a method for determining the extent of differentiation in a population of isolated human embryonic stem cells comprising detecting or measuring two or more markers preferentially expressed in undifferentiated hES cells and one or more markers preferentially expressed after differentiation of the hES cells, wherein the detection comprises assessing the ability of a soluble factor or culture medium to maintain hES cells in an undifferentiated state from said marker expression, classified in class 435, subclass 4.
- V. Claim 16, drawn to a method for determining the extent of differentiation in a population of isolated human embryonic stem cells comprising detecting or measuring two or more markers preferentially expressed in undifferentiated hES cells and one or more markers preferentially expressed after differentiation of the hES cells, wherein the detection comprises assessing the suitability of an undifferentiated hES cell population for preparing differentiated cells for human administration, classified in class 435, subclass 377.

Claims 1 and 14 link(s) inventions I-III. Claims 2, 4-7 and 17-20 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 2, 4-7, 14 and 17-20. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or

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including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups I-V are distinct from each other because they are drawn to materially different methods that differ at least in method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. Methods for determining the extent of differentiation in a population of isolated human embryonic stem cells comprising detecting the marker by antibody assay (group I), detecting the marker by PCR amplification (group II), determining the marker by antibody assay and PCR amplification (group III), by assessing the ability of a soluble factor or culture medium to maintain hES cells in an undifferentiated state from said marker expression (group IV), and by assessing the suitability of an undifferentiated hES cell population for preparing differentiated cells for human administration (group V) are drawn to different scientific considerations in which they have different method steps, reagents and dosages used, and criteria of success etc. They have different classifications and require separate search. Thus, groups I-V are patentably distinct from each other.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'sichen', written in a cursive style.

**SHIN-LIN CHEN  
PRIMARY EXAMINER**